ARGUMENTS

Applicant expresses his appreciation to the Examiner for the thorough and detailed examination of the application. Remaining in the application for consideration are claims 1, 5, 8-11, 14-16, 18-21, 24-26, and 29-34. Claims 32-34 have been allowed and the remaining claims have been rejected. Some of the claims have been rejected under 35 USC §102 based on the Noon, *et al.* reference, some of the claims have been rejected under 35 USC §102 under the Corral reference, some of the claims have been rejected under 35 USC §102 under the Taylor, *et al.* reference, and some of the claims have been rejected under 35 USC §103 based on the Corral reference. Applicant respectfully traverses all of these rejections.

A. The Noon Reference

Considering first the Noon, *et al.* reference, Applicant respectfully disagrees with the Examiner's contention that Noon anticipates claims 1, 9-11, 20, and 24-26. Considering first claim 1, the claim includes the limitation that the sac is soft and compliant and will fill easily with blood to a certain, predetermined volume, but when the sac has reached capacity, no further filling is allowed. Noon simply does not address this issue or the limitations highlighted above. Noon does not express anywhere in his patent the concept of the sac 10 or 12 being filled to a predetermined volume, and when the sac has reached capacity, no further filling is allowed. It is readily apparent why Noon does not mention the limitations on the volume of the sac 10 or 12. Specifically, Noon's sac 10 and 12 are artificial heart chambers themselves. To the extent that the sacs of Noon might be limited in the volume of blood they would receive, that limitation is as a result of the bladder 22 and not as a result of the structure of the sac 10 or 12. It is important to appreciate the claim limitation that the expansion of the sac of the present invention is limited to a "predetermined" volume. The sac is used to help restore an enlarged heart. For that reason, the sac must be limited to a certain

predetermined volume, and after the blood fills the sac to that predetermined volume, no further filling is allowed. Since the sacs of Noon are, in fact, artificial hearts themselves, those sacs could be allowed to expand without a limitation to a predetermined volume. Since the concept of the Noon invention does not in any manner appreciate the need to control the size of the sac, there is no suggestion in Noon of the structural limitation of claim 1 of Applicant's invention that the sac be limited to filling a predetermined volume with no further filling being allowed. It is important to understand that it is the sac that controls the extent of filling and not some additional element surrounding the sac as is the case in Noon.

With the present invention, by limiting the filling of the heart with the sac that is inserted into the ventricle, the ventricle will reverse remodel (i.e. shrink in size) to improve the function of the heart. The heart is not replaced by an artificial heart, but rather the sac is used to allow the heart to repair itself by shrinking to an appropriate size. There is no contemplation whatsoever of the artificial hearts 10-12 of Noon being of a predetermined capacity or volume and upon reaching that capacity, the sac not expanding so that there can be no further filling of the sac. Noon's sacs or artificial hearts 10-12 do not perform this function, do not have this structure and therefore do not anticipate Applicant's invention as set forth in claim 1.

Referring now to claims 9, 10, and 11, the rejection under 35 USC §102 based on Noon is again traversed. In each of these claims, the structural limitation with respect to the size of the sac being at a predetermined capacity is simply not suggested or anticipated by Noon. To the extent that the size of the sacs or artificial heart chambers of Noon are limited in size, that limitation is as a result of the bladder surrounding the heart. There is no suggestion whatsoever that the structure of the sac be such that it will have a limited capacity for receiving a predetermined volume of blood. Of course, it might be acknowledged that any sac that is flexible has a limit on the volume of blood

or other liquid that could be placed in the sac. Certainly an amusement balloon would have a limit on the amount of blood that could be put in the balloon before it would explode. However, that size and volume of blood or liquid that could be put in an amusement balloon is not predetermined. The same argument can be made with respect to Noon. The amount of blood that could be put in the artificial heart of Noon is limited to the extent that there would certainly be a capacity after which the balloon would explode if there was an effort to put an additional volume of blood into the sac, but that volume is unbeknownst to Noon, and Noon does not contemplate establishing on a predetermined basis what that volume would be. Noon certainly does not suggest that when his sac is filled to a predetermined volume, that the size and shape of the sac matches the size and shape of a ventricle of an undiseased human heart. There is simply no suggestion as to what that predetermined capacity is for the Noon artificial heart, nor should there be because Noon is not filling his sac within the ventricle of a human heart and attempting to use that sac in order to reduce the size of an enlarged heart. Noon has no reason to limit the size of his artificial heart sac to the size and shape of an undiseased human heart. That shape could be the size and shape of an enlarged heart and it would not impact Noon's invention. Moreover, there certainly is no suggestion in Noon that the maximum or predetermined volume of blood that can be received in the sac when filled to capacity would cause the sac to appear in the size and shape to match the size and shape of a ventricle of an undiseased human heart. Therefore, claim 9 should be allowed over Noon.

Referring to claims 10 and 11, the same argument can be made that was made in respect to claim 9. Specifically, there is no suggestion in Noon for filling his artificial heart chambers with blood and limiting the capacity of those chambers to a predetermined amount. There is certainly no suggestion as is set forth in claim 11 that the predetermined capacity of the sac or artificial heart of Noon be less than the capacity of the chamber of an enlarged heart. Since Noon is not

contemplating the use of his artificial heart device for reducing the size of an enlarged heart, there is no reason for him to make that suggestion, he does not make such a suggestion, and it cannot be reasonably considered that one of ordinary skill in the art would find from Noon a basis from which to suggest limiting the size of his artificial hearts to a predetermined capacity that is smaller than the chamber of an enlarged heart.

Referring next to claim 20, Applicant respectfully traverses the rejection under 35 USC §102 based on the Noon reference. There is no discussion in the Noon reference of limiting to a predetermined amount the volume of blood that is allowed to enter a chamber of a heart in the diastolic phase of the heart function. The Examiner does not even address this specific limitation of claim 20 in the rejection and it is respectfully submitted that the reason for this oversight is that there is no suggestion for this limitation. Since Noon is addressing a heart problem on a different basis than the Application, there is no reason to think that Noon would suggest limiting to a predetermined amount the volume of blood that is allowed to enter the chamber of a heart in the diastolic phase of the heart function. Once again, this is the structure of the sac in a defined fashion that distinguishes the sac of Applicant's invention from any other references cited by the Examiner.

The Examiner has also rejected claims 24-26 based on Noon under 35 USC §102. Applicant does not concede that with this rejection is justified or appropriate, but as a matter of convenience, Applicant has canceled claims 24-26.

The Corral Reference

The Examiner has rejected claims 1, 5, 8-11, 14-16, 18-21, 24, 29, and 30 under 35 USC §102 as being anticipated by Corral. Applicant respectfully traverses this rejection. Corral contemplates a two-piece ventricular pump that is inserted into either one or both of the hearts ventricles. The two piece device of Corral includes an outer shell typically formed from semi-

flexible plastics. The outer shell is then lined with an inner liner 46 into which the blood flows. However, Corral fails to anticipate or suggests Applicant's invention because the Corral device does not include a sac that is soft and compliant and that will fill easily with blood to a predetermined volume, but when said sac is reached to capacity, no further filling is allowed. Specifically, the structure of the sac of Applicant's invention limits the filling, not a second liner. In the Corral device, the outer shell 44 limits the extent to which the liner 46 can expand. The use of an external device such as the outer shell 44 to limit the ability of the sac to receive a predetermined volume of blood is substantially different from Applicant's invention in which a single element, the sac, limits the volume of blood that can be received in its chamber, and when the sac has reached it capacity as established by the sac, not some outside element, no further filling is allowed. It is the capacity of the sac that limits the amount of blood it receives, not the capacity of the outer shell. Certainly the outer shell does not comply with or meet the definition of Applicant's invention because that device is described as being made from a semi-flexible plastic, not a soft compliant product that is highly flexible. Applicant's invention is a substantial improvement over the Corral device because Applicant's invention eliminates the need for a second part and yet accomplishes its goals by using fewer parts while operating with greater efficiently. Applicant's invention is designed to allow an enlarged heart to regenerate itself and remodel to the size of a normal heart. Corral has no such purpose of his device and will not work to do that. For example, looking at column 6 (beginning at line 12) of Corral, the use of the Corral device in an enlarged heart is described. In that particular case, Corral contemplates sizing the external shell 44 to fit the enlarged ventricle and then the diaphragmatic lining can be volumetrically adjusted to ideal diastolic dimension. The alternate structure described in that paragraph likewise does not anticipate Applicant's invention. But as can be seen from the description in Corral just referenced, the Corral device is not intended to assist

with the remodeling of an enlarged heart. Corral simply substitutes or inserts the outer shell and liner in the ventricle and allows that ventricle to stay enlarged or continue to enlarge. Thus, Corral would never contemplate using the internal liner with a fixed, predetermined volume capacity that would not expand so as to cause the heart to remodel itself when the invention is used as contemplated by Applicant. For the reasons indicated, claim 1 should be allowed over Corral because Corral does not provide a structure that anticipates the claims structure of Applicant. Nothing in Corral suggests the use of a single sac for insertion in a ventricle of a heart with a sac being soft and compliant and fill easily with blood to a certain predetermined volume, but when the sac has reached capacity, no further filling is allowed. The sac limits the capacity to receive a certain predetermined volume of blood, not a sac surrounded by a second shell device as is shown in the Corral reference.

Turning now to claim 5, the rejection of this claim under 35 USC §102 based on Corral is also traversed. Again, the method described in claim 5 contemplates creating a sac of the type described in claim 1. Inserting that sac into a ventricle of a heart and then connecting the openings in the sac to the valves of the heart or to synthetic valves. Once again, this method contemplates a sac that is used as a stand-alone item that will limit the volume of blood entering the ventricle of the heart to a certain predetermined amount. Corral has no such disclosure. Corral discloses a sac that receives the blood, but a second element, the outer shell, controls or limits the amount of volume of blood that comes within the sac and that is a different structure than the structure described by Applicant. Since claim 5 is allowable, claim 8 which depends upon claim 5, should also be allowable. Moreover, claim 8 is allowable independently because there is no suggestion in Corral that the liner be a size and shape so that when filled, it will appear generally in size and shape to match the size and shape of a ventricle of an undiseased human heart. Corral simply does not do

that. Corral's concept is that the outer shell would be enlarged to meet the size of a diseased human heart and the shape and size of the liner is controlled by the filler mechanism, not the structure of the liner.

Referring next to claim 9, the rejection of this claim based on Corral is also traversed. There is no disclosure that describes the liner of Corral as having a capacity for receiving a predetermined volume of blood and said sac when filled to capacity would appear generally in the size and shape to match the size and shape of a ventricle of an undiseased human heart. There is no predetermined capacity or size for the liner of Corral. The capacity and size of that liner is controlled by the outer shell, not by the flexible sac or liner itself. Moreover, the size and shape of the sac or liner of Corral when filled is unknown because we do not know when it is filled and when it is not filled to its maximum capacity. The maximum amount of blood it can receive may be defined by the outer shell, but that does not mean that the sac has reached its maximum capacity nor does it describe the shape in which the sac would form if it were allowed to filter its maximum capacity. Again, it is the sac that has the predetermined capacity and shape in the Applicant's invention whereas in Corral, the liner has no predetermined size or shape but rather the size or shape of the liner is controlled by the outer shell.

Claim 10 has also been rejected based on Corral and that rejection is traversed. As has been pointed out in great detail and specificity above, Applicant's sac has a predetermined capacity that limits the amount of blood that can be received in the sac. In Corral, there is no discussion of the capacity of the liner of Corral nor is there any discussion that the liner has a predetermined capacity that limits the amount of blood that can be received in the liner. Rather, the liner of Corral is a somewhat amorphous product that could be filled to any variable capacity that would have any of a variety of shapes apparently, but for the outer shell that does control to some extent the size and

shape of the liner. However, it is not the sac itself that has a predetermined capacity or that limits the amount of blood it can be received in the sac; rather it is the shell that performs those functions and that is different from the invention claimed by Applicant.

With respect to claim 11, since it depends from claim 10, it should be allowable because claim 10 is allowable over the references cited by Examiner. Also, claim 11 should be allowable on its own independent merit, because there is certainly nothing in Corral that discusses that the predetermined capacity of the sac being less then the capacity of the chamber of an enlarged heart. In fact, the contrary is suggested by Corral. Corral suggests that in order to keep the sac from getting bigger, he must make the shell bigger or he must increase the amount of fluid that is pumped into the space between the outer shell and the liner (see column 6 beginning at line 12). That description by Corral certainly suggests that the liner of Corral has a predetermined capacity that is the size of the chamber of the enlarged heart rather than less than the capacity of the chamber of an enlarged heart. For that reason, claim 11 should also be allowed.

Turning now to claims 14, 15, and 16, the rejection of these claims based on Corral is also traversed. Corral does not discuss in any manner a method of reducing stress on the walls of a chamber of a heart by inserting a flexible sac in a chamber of the heart with said sac having a predetermined maximum capacity. Corral talks about a liner that fits within an outer shell. Corral's liner is not described as having any predetermined maximum capacity. The capacity of the liner is limited because of the outer shell, but that does not mean that the sac itself has a predetermined maximum capacity or certainly doesn't suggest a maximum capacity that is of a volume that would cause the sac to exert only minimal pressure on the walls of a chamber of the heart. If the liner of the Corral patent were filled to maximum capacity, we don't know from the Corral disclosure what that is. We know it is limited in the amount that can be filled because of the outer shell. However,

we do not know what the maximum capacity of the sac itself is and certainly it would appear that since there is a need for an outer shell in the Corral device, the maximum capacity of the liner of Corral would put more than minimal pressure on the walls on the chamber of the heart if the liner were filled to maximum capacity. There is certainly nothing suggested in Corral, as is claimed in claim 16, that the sac, when filled to maximum capacity, would exert less pressure on the walls on the chamber of the heart than would be exerted if the sac had not been used. It is not the sac in Corral that limits the pressure that is applied to the walls of the chamber of the heart. It is the outer shell and the outer shell is not indicated by the Examiner to be the feature that is being considered as meeting the limitations of Applicant's claims. The Examiner refers to the inner liner as being the part of the disclosure of Corral that the Examiner believes anticipates Applicant's invention. That being the case, it is quite clear that the liner does not perform the function or the steps of the method as described in claims 14, 15, and 16. For that reason, the rejection of these claims based on Corral should be withdrawn.

Turning now to claims 18 and 19, these claims have been rejected under 35 USC §102 based on Corral, and for the same reasons as been stated with respect to claims 14-16, claims 18 and 19 should be allowed. While Corral does use the outer shell to limit the volume of blood that is allowed to enter the chamber of a heart in the diastolic phase, there is no description in Corral that the predetermined quantity of blood that is allowed to enter the chamber is selected so there is minimal pressure on the walls of the chamber. With respect to claim 19, the disclosure of Corral does not address any difference between the volume of blood that is allowed to enter the chamber of the heart as between the diastolic phase and the systolic phase. When the chamber of the heart is dilated, the volume of blood that is allowed to enter the outer shell of the Corral device is no different than the amount of blood that is allowed to enter the outer shell when the chambers in the

systolic phase. Furthermore, to the extent that the amount of blood that is in the chamber of the heart when using the Corral device is different that the diastolic and systolic phase, that difference is controlled by the liner, not by the outer shell. Therefore, it is apparent that the limitations of claims 18 and 19 are not anticipated by the Corral disclosure.

Referring now to claims 20 and 21, these claims have been rejected under 35 USC §102 based on Corral and that rejection is also traversed. The liner of the Corral device does not limit to a predetermined amount the amount of blood that is allowed to enter the chamber of a heart in the diastolic phase of the heart function. It is the outer shell that does that limitation, and the flexible sac (the inner liner that the Examiner refers to) does not limit the volume of blood that is allowed to enter the chamber of the heart in the diastolic phase. With respect to claim 21, Corral does not disclose a method of treating a diseased heart by inserting a flexible sac into the chamber of the heart with the sac limiting to a predetermined volume the amount of blood that is allowed to enter the chamber in the diastolic phase of the heart function. It is the outer liner that limits the amount of blood that is allowed to enter the chamber of the heart in the diastolic phase in Corral, not the liner. For that reason, claim 21 should be allowed.

Referring next to claims 29, 30 and 31, these claims have been rejected based on Corral either under 35 USC §102 (claims 29 and 30) or §103 (claim 31). Applicant respectfully traverses these rejections. The methods described in claims 29, 30, and 31 are similar to the methods of claims 32, 33, and 34. Again, these methods all contemplate treatment of heart disorders by inserting the sac of claim 20 in the heart and connecting the sac to the anulus of the inflow and outflow valves of the chamber. Applicant respectfully submits that the method of reducing the likelihood of an enlargement of a cardiac chamber by inserting the sac of claim 20 in the heart and connecting the sac to the anulus of the inflow valve and the anulus of the outflow value of the

chamber is not suggested by Corral either as a stand-alone feature or as an addition to a conventional operation of the heart. There is no suggestion whatsoever of this methodology in Corral. Likewise, there is no suggestion in Corral of a method of treating a left ventricular aneurism by inserting the sac of claim of 20 in the left ventricle of the heart in addition to a step of conventional operative repair of a left ventricular aneurism. There is no suggestion whatsoever of using the sac of claim 20 to either reduce the likelihood of heart enlargement either as a stand-alone item or as an additional feature to conventional treatment of these maladies of the heart. Corral does not make that suggestion and the rejection of claims 29, 30, and 31, is respectfully submitted, should be withdrawn.

The Taylor Reference

The Examiner has also rejected claims 9-11, 18-21, and 30 and 31 under 35 USC §102(b) as being anticipated by Taylor, *et al.* Applicant respectfully traverses this rejection. Applicant respectfully suggests the disclosure of Taylor does not anticipate the claims. Specific, looking at claims 9, 10, and 11, Taylor does not show a flexible sac having a capacity for receiving a predetermined volume of blood and when filled to capacity, the sac would appear generally in the size and shape to match the size and shape of the ventricle of an undiseased human heart. When the sac 113 of the Taylor invention is filled to capacity, it simply takes up volume in an enlarged heart; it does not match the size and shape of an undiseased human heart. The Taylor sac is never filled with blood; rather it is filled with saline fluid, water, or other well-known inflation fluid (see page 9, paragraph 86 of the Taylor reference). The sac of Taylor also does not have a predetermined capacity. There is no suggestion whatsoever in Taylor that the sac has a predetermined capacity. Moreover, there is no suggestion that the sac is filled with blood once inserted into the chamber of a heart, and in fact, the sac does not receive the blood; rather, it is simply for the purpose of reducing

the ventricular or dead space of an enlarged heart. Applicant's invention controls blood flow in the ventricle to predetermined amounts as opposed to reducing the ventricle, or dead space within, the enlarged heart.

The rejections of claims 18-21 based on Taylor is also inappropriate and unfounded and should be withdrawn. The methods of claims 18 through 21 involves the treatment of a diseased heart and the process for the treatment of a diseased heart that involves the insertion of a flexible sac into a chamber of the heart with the sac limited to a predetermined volume of the amount of blood that is allowed to enter the chamber of the heart. The sac of Taylor reduces the amount of volume of blood that is allowed to enter the chamber of the heart, but it does not limit it to a predetermined volume because the walls of the heart could expand under pressure and therefore cause the heart chamber to continue to receive more and more blood as the heart enlarges. Furthermore, the device of Taylor does not minimize the pressure on the walls of the heart chamber; rather, it is more likely the device of Taylor would increase the pressure on the walls of the heart chamber.

With respect to claims 30 and 31, rejection of these claims based on Taylor is also traversed. There is no suggestion whatsoever in Taylor for a method of reducing the likelihood of enlargement of a cardiac chamber by inserting a sac such as the one claimed in claim 20 in the chamber of the heart in addition to a conventional operation of the heart; or as an additional step to the conventional operative repair of a left ventricular aneurism. Taylor only contemplates using his invention once the heart is enlarged, not as a method of controlling the likelihood of the enlargement of the heart. In fact, Taylor's invention would only work once the heart is enlarged because he inserts a sac into the enlarged chamber of the heart and blows the sac up so that it reduces the remaining volume in the chamber of the heart. Conversely, Applicant's invention is a sac inserted into the chamber of the heart with the blood flowing into the sac to limit and control the amount of blood that goes into

the chamber so that the pressure of the blood will not cause the heart to enlarge. There is no suggestion in Taylor of using the sac described in his patent as an addition to the step of the conventional operative repair of a left ventricular aneurism. In fact, Taylor's device could not function in that manner. If there were an aneurism of the left ventricle, placing the Taylor sac into the heart to take up volume would only increase the pressure at the point of damage where the aneurism has occurred and be more likely to cause serious additional damage to the patent if not death. Applicant's invention on the other hand, receives the blood into the sac so that even if there is an aneurism of the heart's left ventricular chamber, the pressure of the blood coming into the chamber does not increase the likelihood of further tearing at the point where the aneurism has already occurred. For these reasons, it is respectfully submitted the claims of 30 and 31 are patentable over Taylor and Taylor does not anticipate the invention as claimed in these claims.

CONCLUSION

Applicant believes he has addressed each and every objection and rejection in the application as stated by the Examiner and has obviated each rejection so that the claims have been shown to be patentable over the current references as cited and applied. If the Examiner feels that there continues to be some question about the patentability of the claims as presented, and believes that some minor modifications to the claims might be appropriate to overcome those points he still has reservation about, he is invited to contact the undersigned to discuss the claims so that the application can be put in condition for allowance.